EPA United States Environmental Protection Agency

RCRA Compliance Branch

INSPECTION REPORT TEMPLATE

Inspection Date(s):	07/31/2018	**Inspection Announced:** No
Facility or Site Name:	Boston Scientific	
Facility/Site Physical Location:	Road 698 Lot 12	
(city, state, zip code)	Dorado, Puerto Rico 00646	
Mailing address (if different from above):	N/A	
(city, state, zip code)	N/A	
Facility/Site Contact:	Ariel Gonzalez	EHS Manager
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RCRA ID Number:	PRD987370723	
Facility/Site Personnel Participating in Inspection:		
Ariel Gonzalez	Above	Above
Eladimar Picon	EHS Specialist	N/A
Inspector(s):		
William Chernes		
Supervisor:		
Derval Thomas		

SECTION I – INTRODUCTION

Purpose of the Inspection Objective

The purpose of the inspection was to determine a facility's compliance with the Resource Conservation and Recovery Act. The inspection was conducted by an EPA RCRA inspector and was prompted due to the facility's inspection history.

Opening Conference

EPA Region 2 RCRA inspector William Chernes arrived at Boston Scientific on July 31, 2018 for an unannounced inspection. I displayed my credentials to a guard (did not disclose name) at the security checkpoint. The security guard contacted Ariel Gonzalez, EHS Manager. I met with Ariel Gonzalez, Eladimar Picon, EHS Specialist, and Paul Martin, VP Operations for the opening conference of the inspection. I presented my credentials to Ariel Gonzalez, Eladimar Picon, and Paul Martin and informed them that this was an EPA inspection to determine the facility's compliance with RCRA. The scope of the inspection is a compliance evaluation inspection (CEI).

Facility/Site Description

Boston Scientific is a manufacturing facility that creates electrical leads for the medical industry. The electrical leads are used for cardiac rhythm management, alleviation of Parkinson's disease symptoms, and pain management (neuromodulation).

The facility's primary hazardous waste generation is from manufacturing in clean rooms. The hazardous waste is typically Isopropyl Alcohol (D001) and Isopropyl Alcohol containing wipes (D001). There were three clean rooms in operation at the time of the inspection. The clean rooms each contain about ten 5-gallon satellite accumulation containers. Hazardous waste and universal waste is stored in one central storage area. After review of the manifest information and statements made by the facility representatives it was determined that the facility was a Large Quantity Generator (LQG) at the time of the inspection.

SECTION II – OBSERVATIONS

Room B

Room B is used as an intermediary storage area for satellite accumulation hazardous wastes that are generated in Clean Room B. The hazardous wastes generated in the clean room is brought to this room (which is directly attached to the clean room) and stored until the end of the day. The hazardous wastes are temporarily stored in this area to maintain production efficiency and are brought to the 90-day central storage area at the end of each operating day. The wastes (hazardous and non-hazardous) are all stored within secondary containment and there is a fire suppression system in place. The wastes observed in this area were as follows:

- Two 5-gallon satellite containers of hazardous waste isopropyl alcohol that were both closed and labeled.
- One 55-gallon satellite container of hazardous waste isopropyl alcohol containing wipes that was closed and labeled.
- Three 35-gallon drums of non-hazardous waste that were closed and labeled.
- One 5-gallon container of non-hazardous waste that was closed and labeled.

Clean Room B

Clean Room B is used for manufacturing of medical leads. The area is restricted access unless employees wears the proper Personal Protective Equipment (PPE) to prevent contamination of manufactured products. There were ten 5-gallon satellite accumulation containers in this area, all the containers were closed and labeled at the time of the inspection.

Room A

Room A serves the same function as Room B, stated above. The area is used as an intermediary storage area for satellite accumulation hazardous wastes that are generated in Clean Room A. The hazardous wastes generated in the clean room is brought to this room (which is directly attached to the clean

room) and stored until the end of the day. The hazardous wastes are temporarily stored in this area to maintain production efficiency and are brought to the 90-day central storage area at the end of each operating day. The wastes (hazardous and non-hazardous) are all stored in secondary containment and there is a fire suppression system in place. The wastes observed in the area were as follows:

- Two 5-gallon satellite containers of hazardous waste isopropyl alcohol that were both closed and labeled.
- One 5-gallon satellite container of hazardous waste aerosols that was closed and labeled.
- One 55-gallon satellite container of hazardous waste isopropyl alcohol containing wipes that was closed and labeled.
- Two 35-gallon non-hazardous waste drums that were closed and labeled.

Clean Room A

Clean Room A is used to manufacture medical leads for the brain (neuromodulators). The wires used in the manufacturing process are purchased as raw materials. The other components for the medical lead product such as tubing and wire ends are manufactured within the clean room. There were ten 5-gallon satellite accumulation containers for isopropyl alcohol wastes in this area, all the containers were closed and labeled at the time of the inspection.

Clean Room C

Clean Room C was temporarily shut down for maintenance at the time of the inspection. There was no hazardous waste generation in this area at the time of the inspection. When in operation this clean room generates less hazardous waste due to a new automated system that is in place.

Clean Room D

Clean Room D shares a similar function to Clean Room A, stated above. This room is used to manufacture a medical lead product that is used for cardiac rhythm treatment. At the time of the inspection, there were ten 5-gallon satellite accumulation containers present in this room; all the satellite containers were closed and labeled.

Antechamber C/ D

Antechamber C/D is used similarly to Room A and Room B and functions as an intermediary storage area for satellite accumulation wastes that are generated in Clean Room C and D. The hazardous wastes are temporarily stored in this area to maintain production efficiency and are brought to the 90-day central storage area at the end of each operating day. The wastes (hazardous and non-hazardous) are all stored within secondary containment and there is a fire suppression system in place. The wastes observed in this area were as follows:

- Six 5-gallon satellite containers of hazardous waste isopropyl alcohol that were closed and labeled.
- Two 55-gallon satellite containers of hazardous waste isopropyl alcohol containing wipes that were both closed and labeled.

90-Day Central Storage Area

The 90-Day Central Storage Area is maintained by Jonathan Malendez, EHS Technician. Mr. Malendez is responsible for this area and he also brings all the accumulated satellite wastes to the central storage area at the end of each operating day. The central storage area is fully enclosed and under a fire suppression system and exhaust system. The entire central storage area is within secondary containment, and has a communication device with an emergency contact list readily available. Mr. Malendez separates the hazardous wastes by physical properties (solids are stored in one area and liquids are stored in another). Hazardous waste drums that are being actively filled are grounded via grounding wire which are attached to the storage area walls. Universal wastes are also stored in this area but are handled as hazardous wastes. The hazardous wastes that were present in the central storage area at the time of the inspection were as follows:

- Seven 55-gallon drums of isopropyl alcohol that were all closed, labeled and dated. The drums were also grounded.
- Three 5-gallon containers of aerosols that was closed, labeled, and dated.
- One 55-gallon container of Lead-Acid Batteries (handled as hazardous waste) that was closed, labeled, and dated.
- Three 55-gallon drums of isopropyl alcohol (actively being filled) that were closed, labeled, dated. The three drums were also grounded.
- Fourteen 55-gallon drums of isopropyl alcohol containing wipes that were closed, labeled, and dated.
- Three 5-gallon buckets of Lithium Ion Batteries (handled as hazardous waste) that were closed, labeled, and dated; the terminals were all taped.

Quality Assurance Laboratory

The Quality Assurance Laboratory is used to test product specifications, test for clean room organism content, and determine clean room/ product cleanliness. Lorraine Alicea, Lab Manager, oversees this lab. The hazardous waste observed at the time of the inspection was as follows:

- Two 5-gallon satellite accumulation containers of HPLC waste that were both closed and labeled.
- One 5-gallon satellite accumulation container of isopropyl alcohol containing wipes that was closed and labeled.
- One 5-gallon satellite accumulation bucket of HPLC waste vials that was closed and labeled.
- One 5-gallon satellite accumulation container of isopropyl alcohol that was closed and labeled.

Chemical Storage Area for Quality Assurance Laboratory

This area is used to store all the virgin materials used in the Quality Assurance Laboratory. There was no hazardous waste present in this area at the time of the inspection.

Record Review

- Manifests and Land Disposal Restrictions

After review of the manifest and land disposal restriction documentation, there were no discrepancies to report.

- Contingency Plan

The contingency is available online and in paper form. The contingency plan was sufficient, documented, and up-to-date.

- Weekly Container Storage Area Inspections

The weekly container storage area inspections were all accounted for. The facility also inspects all the satellite accumulation antechambers. The antechambers are compliant with 90-day storage standards and container the required safety equipment such as fire extinguisher, spill kits, and communication devices.

- Arrangements with the Local Authorities

The facility has made arrangements with all the required authorities. The arrangements were made in 2015 and there have been no updates on the contingency plan.

- Personnel Training

The facility uses an online tracking and training program in order to maintain proper training intervals and recordkeeping. The hazardous waste training is given to all clean room and lab personnel annually. The EHS staff is also trained and receive the 8-hour HAZWOPER refresher training annually.

SECTION III – AREAS OF CONCERN

The presentation of areas of concern does not constitute a formal compliance determination or violation.

I observed no areas of concern at the time of the inspection.

Closing Conference

A closing conference was held with USEPA inspector William Chernes, and the facility representatives Ariel Gonzalez, Eladimar Picon, and Paul Martin. During the closing conference USEPA Inspector William Chernes reviewed the inspection process stated that there were no areas of concern at the time of inspection.

Signatures:

_____ _____

Inspector Date

_____ _____

Section Chief Date